UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,959	02/12/2002	Avery J. Evans	SPEC-6150	6989

7590 01/22/2007

Allegiance Corporation
Attn: Kim Diliberti
1430 Waukegan Road
McGaw Park, IL 60085-6787

EXAMINER	
RAMANA, ANURADHA	
ART UNIT	PAPER NUMBER
3733	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/074,959	EVANS ET AL.	
	Examiner	Art Unit	
	Anu Ramana	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 21-32* is/are pending in the application.

4a) Of the above claim(s) *28* is/are withdrawn from consideration.

5)☒ Claim(s) *6-9 and 17-19* is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 15-16, 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Neiimeister et al. (US 4,560,352).

Neiimeister et al. disclose a dispenser assembly for dental compositions including: a plunger assembly having a shaft 46 with a threaded middle portion, a handle 51 attached to a first end of the shaft; a dispenser hub assembly including a collar 45 and a hand-grip 61 attached to the collar; and a hollow tube or casing 4(Fig. 2, col. 3, lines 8-68, col. 4 and col. 5, lines 1-20).

Claims 1-2, 10, 15-16, 29 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Preissman (US 6,383,190).

Preissman discloses a system for delivery of bone cement including: a plunger assembly with a shaft 76' having a threaded middle section and a handle 72 attached to a first end of the shaft; a dispenser hub assembly having a collar with an internally threaded portion and a handle 75; a hollow tube 74' removably engaged with the dispenser hub assembly; and a sealing element such as an O-ring 77' mounted on the shaft (Figs. 10-12C, 18, col. 11, lines 62-67, col. 12, col. 13, lines 1-13, col. 14, lines 11-67). Also see marked up Figure 11 on the following page.

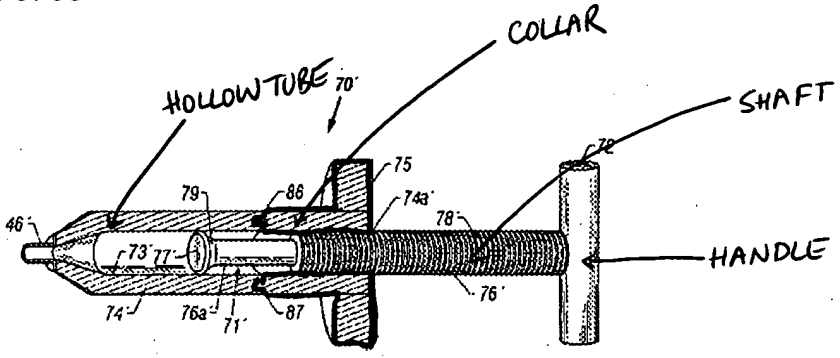

FIG. 11

Claims 1-2, 10, 15, 16, 29 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Pierson et al. (US 6,571,992).

Pierson et al. disclose a syringe for dispensing pastes and putties, for e.g. dental restoratives, i.e., bone cement, including: a plunger having a shaft with a threaded middle portion, a handle 90 attached to a first end of shaft 70 and a piston or "unthreaded second end" 80; and a dispenser hub assembly wherein the hub assembly includes a collar 60 with a threaded portion 63 and a hand grip 51 attached to the collar (Figs. 1, 2 and 6, col. 2, lines 52-67, col. 3 and col. 4, lines 1-51).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4 and 5 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Preissman (US 6,383,190) in view of Mazur et al. (US 5,401,246).

Preissman discloses that O-ring 57 is mounted on the plunger but is silent as to how the O-ring is mounted on the plunger.

Mazur et al. teach an O-ring 57 mounted on a plunger by placing the O-ring in a groove 49 on the plunger, the groove having sufficient width and depth to prevent the O-ring from rolling over and out of groove 49 (col. 6, lines 16-43).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have mounted the O-ring on the plunger of the Preissman device by placing the O-ring in a groove in the plunger, as taught by Mazur et al., to prevent the O-ring from rolling over and out of the groove.

Claims 11-12 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Preissman (US 6,383,190).

Preissman discloses that pressure applicator 50 is formed of clear nylon or other chemically compatible material and that the volume is preferably 10 cc and up to contain sufficient implant material (col. 10, lines 26-29 and col. 14, lines 58-64).

Regarding claim 11, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have made applicator 70' with column 74' approximately 10 cc in volume, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Regarding claims 12 and 31, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed pressure applicator 70' of clear nylon since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use, herein compatibility, as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claims 12, 13, 31 and 32 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Preissman (US 6,383,190) in view of LeVeen et al. (US 4,312,343).

Preissman discloses all elements of the claimed invention except for graduations on hollow tube 74'.

LeVeen et al. teach the barrel of a syringe being made of a transparent material and volume graduation markings on the barrel (col. 2, lines 29-38).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided volume graduation markings on the Preissman hollow tube to indicate the volume of material contained within.

Claim 14 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Preissman (US 6,383,190) in view of Fischer (US 5,603,701).

Preissman discloses all elements of the claimed invention except for handle 92 being ergonomically shaped.

Fischer teaches knob 80 of a syringe apparatus to be shaped to facilitate ease of gripping and manipulation by the user with a minimal amount of wrist rotation (col. 5, lines 46-54).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided an ergonomically shaped hand knob in the Preissman apparatus, as taught by Fischer for ease of manipulation by the user.

Claims 4 and 5 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Pierson et al. (US 6,571,992) in view of Mazur et al. (US 5,401,246).

Pierson et al. disclose all elements of the claimed invention except for a sealing means such as an O-ring disposed in a groove in plunger 70.

Mazur et al. teach an O-ring 57 mounted on a plunger by placing the O-ring in a groove 49 on the plunger, the groove having sufficient width and depth to prevent the O-ring from rolling over and out of groove 49 (col. 6, lines 16-43).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have mounted the O-ring on the plunger of the Preissman device by placing the O-ring in a groove in the plunger, as taught by Mazur et al., to prevent the O-ring from rolling over and out of the groove.

Claim 3 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Pierson et al. (US 6,571,992) in view Preissman (US 6,383,190).

Pierson et al. disclose all elements of the claimed invention except for an enlarged funnel-shaped opening at a first end of the hollow tube.

Preissman teaches providing an enlarged introduction section so that a plunger may be introduced into the implant material or bone cement without formation of a seal (col. 17, lines 9-65).

Accordingly, it would have also been obvious to one having ordinary skill in the art at the time the invention was made to have provided an enlarged introduction section in the Pierson et al. applicator, as taught by Preissman, so that a seal is not formed when a plunger is introduced into material in the applicator.

Claim 11 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Pierson et al. (US 6,571,992).

Pierson et al. disclose all elements of the claimed invention except for the volume of barrel 20 to be 10 cc.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have made barrel 20 with a volume of 10 cc, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claims 12-13 and 31-32 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Pierson et al. (US 6,571,992) in view of LeVeen et al. (US 4,312,343).

Pierson et al. disclose all elements of the claimed invention except for barrel 20 being made of a transparent material and graduations on barrel 20.

LeVeen et al. teach the barrel of a syringe being made of a transparent material and volume graduation markings on the barrel (col. 2, lines 29-38).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided volume graduation markings on the Pierson et al. barrel to indicate the volume of material contained within.

Claim 14 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Pierson et al. (US 6,571,992) in view of Fischer (US 5,603,701).

Pierson et al. disclose all elements of the claimed invention except for handle 90 being ergonomically shaped.

Fischer teaches knob 80 of a syringe apparatus to be shaped to facilitate ease of gripping and manipulation by the user with a minimal amount of wrist rotation (col. 5, lines 46-54).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided an ergonomically shaped hand knob in the Pierson et al. apparatus, as taught by Fischer for ease of manipulation by the user.

Claims 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhatnagar et al. (US 6,395,007) in view of Preissman (US 6,383,190).

Bhatnagar et al. disclose a kit having a cement delivery means 42, a tubing assembly 44 removably attached to the cement delivery means 42, a cannula 12, a stylet 2, a hammer and a forceps (Fig. 4, col. 5, lines 31-66, col. 6, lines 1-35, col. 8, lines 45-59, col. 9, lines 46-67, col. 10, lines 1-26 and lines 55-61).

Bhatnagar et al. further disclose that any cement delivery means could be used (col. 9, lines 7-17).

Bhatnagar et al. disclose all elements of the claimed invention except for a cement delivery means including a plunger assembly and a dispenser hub assembly disposed around the shaft.

Preissman teaches a cement delivery means having a plunger assembly with a shaft and a handle attached to an end of the shaft and a dispenser hub assembly around the shaft (see previous discussion of Preissman).

It would have been obvious to one of ordinary skill in the art at the time the invention was made have substituted a cement delivery means as, for example, taught by the Preissman reference for the cement delivery means in the Bhatnagar et al. kit wherein so doing would amount to mere substitution of one functionally equivalent

structure for another within the same art and the selection of any of these devices would work equally well in the claimed device.

Claims 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhatnagar et al. (US 6,395,007) in view of Hawkins et al. (US 5,638,997).

Bhatnagar et al. disclose a kit having a cement delivery means 42, a tubing assembly 44 removably attached to the cement delivery means 42, a cannula 12, a stylet 2, a hammer and a forceps (Fig. 4, col. 5, lines 31-66, col. 6, lines 1-35, col. 8, lines 45-59, col. 9, lines 46-67, col. 10, lines 1-26 and lines 55-61).

Bhatnagar et al. further disclose that any cement delivery means could be used (col. 9, lines 7-17).

Bhatnagar et al. disclose all elements of the claimed invention except for a cement delivery means including a plunger assembly and a dispenser hub assembly disposed around the shaft.

Hawkins et al. teach a cement delivery means having a tube 24 filled with bone cement removably attached to a cement injector gun wherein the gun has a plunger assembly, the plunger assembly having a handle 4 and a shaft 1 and a dispenser hub assembly around the plunger assembly (Fig. 1, col. 2, lines 64-67and col. 3, lines 1-47).

It would have been obvious to one of ordinary skill in the art at the time the invention was made have substituted a cement delivery means as, for example, taught by the Hawkins et al. reference for the cement delivery means in the Bhatnagar et al. kit wherein so doing would amount to mere substitution of one functionally equivalent structure for another within the same art and the selection of any of these devices would work equally well in the claimed device.

Claims 21 and 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chin (US 5,156,606) in view of Hawkins et al. (US 5,638,997).

Chin discloses a kit including a cement delivery means and a slap hammer 22 (Fig. 1 and col. 3, lines 34-52).

Chin discloses all elements of the claimed invention except for the cement delivery means having a tube with bone cement removably attached to a dispenser hub assembly when the shaft is attached to the dispenser hub assembly.

Hawkins et al. teach a cement delivery means having a tube 24 filled with bone cement removably attached to a cement injector gun wherein the gun has a plunger assembly, the plunger assembly having a handle 4 and a shaft 1 and a dispenser hub assembly around the plunger assembly (Fig. 1, col. 2, lines 64-67and col. 3, lines 1-47).

It would have been obvious to one of ordinary skill in the art to substitute a cement delivery means as, for example, taught by the Hawkins et al. reference for the cement delivery means of the Chin kit wherein so doing would amount to mere substitution of one functionally equivalent cement delivery means for another within the same art and the selection of any of these devices would work equally well in the Chin kit.

Claims 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chin (US 5,156,606) and Hawkins et al. (US 5,638,997) further in view of Preissman (US 6,383,190).

The combination of Chin and Hawkins et al. discloses all elements of the claimed invention except for a tubing assembly, a luer fitting, a cannula and a stylet for insertion into the cannula.

Preissman teaches providing a tubing assembly including: a tubing assembly 11, luer fitting 52, a stylet 2 and a cannula 10 for delivery of implant material at a site (col. 8, lines 20-56).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a tubing assembly, luer fittings, stylet and cannula, as taught by Preissman, in the kit of the combination of Chin and Hawkins et al., as taught by Preissman, for the purpose of delivery of implant material to a specific site.

Response to Arguments

Applicant's arguments submitted under "REMARKS" in the response filed on October 30, 2006 have been fully considered.

Applicants' arguments regarding the rejections under 35 USC 102(b) based on Neiimeister et al. are not persuasive because Applicants' arguments are directed to features that are not claimed. Contrary to Applicants' arguments, during examination, claims must be interpreted as broadly as their terms reasonably allow. This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). Finger 51 is a part that can be held by a hand and thus meets that definition of a handle.

Applicants' arguments regarding the rejections under 35 USC 102(b) based on Preissman are not persuasive. Preissman clearly shows that collar 82 is provided with a hinge pin 84 which is insertable into a recess 86 in column 74' for pivoting therewith or allowing removal of the section altogether (col. 12, lines 49-56). Thus, hollow tube 74' is removably attached to the dispenser hub assembly.

Applicants' arguments regarding the rejections under 35 USC 102(b) based on Pierson et al. are not persuasive because Fig. 1 clearly shows collar 60 to be attached or joined to hand grip 51.

Regarding the rejections under 35 USC 103(a), it is noted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). The basis for the various rejections has been clearly explained by the Examiner in the rejections made in this office action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR
January 16, 2007